

REMARKS

The Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

35 U.S.C. §103(a) Rejection – Gillies, Werp

Claims 1, 4-10, 13-24, 27-35, and 38-49 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,272,370 issued to Gillies (hereinafter “Gillies”) in view of U.S. Patent No. 6,152,933 issued to Werp (hereinafter “Werp”). Without admitting that these references could or should be combined, the Applicants respectfully submit that the present claims are allowable over Gillies and Werp.

Claim 23 recites:

“A method comprising:

inserting a medical device into an anatomy, the medical device having a plurality of target markers;

storing information for the medical device and the plurality of target markers in a memory prior to insertion of the medical device into the anatomy;

scanning a magnetic resonance image (MRI) of the anatomy;

processing the scanned image by a MRI processor coupled to the memory;

determining a location and orientation of the medical device inserted in the anatomy in relation to the anatomy based on the plurality of target markers; and

displaying an image of the medical device within the anatomy, including superimposing the medical device on the anatomy using the information for the medical device stored in the memory prior to insertion of the medical device into the anatomy”.

Gillies and Werp do not disclose these limitations or render them obvious. In particular, Gillies and Werp do not disclose or render obvious “***storing information for the medical device and the plurality of target markers in a memory prior to insertion of the medical device into the anatomy***” and “***displaying an image of the medical device within the anatomy, including***

superimposing the medical device on the anatomy using the information for the medical device stored in the memory prior to insertion of the medical device into the anatomy”.

Gillies discusses in part a magnetic resonance (MR)-visible medical device for neurological interventions using nonlinear magnetic stereotaxis and a method of imaging. See e.g., the Title. Gillies discusses in part that magnetic resonance (MR) imaging may be used for guidance. See e.g., column 6, lines 25-26. Gillies discusses in part at column 8, lines 15-35 that medical device may have MR-visible markers.

Gillies, however, does not teach, disclose or suggest “*storing information for the medical device and the plurality of target markers in a memory prior to insertion of the medical device into the anatomy*” and “*displaying an image of the medical device within the anatomy, including superimposing the medical device on the anatomy using the information for the medical device stored in the memory prior to insertion of the medical device into the anatomy*”.

At column 11, lines 1-40, Gillies discusses in part fitting a patient with fiducial markers that are fixed to the skull and giving a patient a pre-operative brain scan to form an atlas of images that define the location of critical brain structures. The atlas of images of the brain may be stored in a computer system. Images resulting from a bi-planar fluoroscopy system are superimposed and registered onto the pre-operative MR brain scan.

However, the atlas of images that define the location of critical brain structures from the pre-operative brain scan are not “*information for the medical device and the plurality of target markers (of the medical device)*”. There is no disclosure of “*superimposing the medical device on the anatomy using the information for the medical device stored in the memory prior to insertion of the medical device into the anatomy*”.

Gillies simply does not disclose or contemplate storing information for the medical device and the plurality of target markers in a memory prior to insertion of the medical device into the anatomy, and displaying an image including superimposing the medical device on the anatomy using the information for the medical device stored in the memory. Rather, Gillies seems to disclose an alternate approach, such as including **microcoils** to help improve imaging

of the device (see e.g., FIG. 3 and column 23, line 35) and/or **variably adjusting** MR visibility based on requirements so that the device is visible (see e.g., column 8, lines 23-31 and column 23, lines 37-38).

Accordingly, Gillies does not disclose the limitations of claim 23. Werp does not remedy all of what is missing from Gillies.

Werp discusses in part an intracranial bolt and method of placing and using an intracranial bolt to position a medical device. See e.g., the Title. At column 3, lines 15-25, Werp discusses:

“The cap preferably includes a socket 43 for mounting a marker 45. The marker 45 is preferably a hollow body that can be filled with a substance, such as vitamin e, that is opaque (but non-distorting) to magnetic resonance imaging. The marker provides a clear indication of the location and orientation of the intracranial bolt, which is otherwise transparent to magnetic resonance imaging, so that in a preprocedure magnetic resonance image, the path of the medical instrument through the intracranial bolt and into the brain can be planned in advance”

However, Werp does not teach, disclose or suggest “***storing information for the medical device and the plurality of target markers in a memory prior to insertion of the medical device into the anatomy***” and “***displaying an image of the medical device within the anatomy, including superimposing the medical device on the anatomy using the information for the medical device stored in the memory prior to insertion of the medical device into the anatomy***”.

There is absolutely no mention whatsoever in Werp of storing information for a medical device prior to insertion of the medical device and displaying an image including superimposing the medical device on the anatomy using the stored information. As understood by Applicants, Werp does not even mention superimposing or storing information for a medical device in a memory. Moreover, since the marker 45 is apparently reported as being visible and is outside of the patient (see e.g., FIG. 6a), there would be no apparent reason to practice the method of claim 23, and the Examiner has not provided sufficient reasoning why there would be.

Accordingly, for at least one or more of these reasons, claim 23, and its dependent claims, are believed to be allowable.

Claim 1 recites:

“An apparatus comprising:

a medical device adapted to be inserted into an anatomy; and

a plurality of target markers disposed on a proximal portion of the medical device,

wherein geometric information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system”.

Gillies and Werp do not disclose these limitations or render them obvious. In particular, Gillies and Werp do not disclose or render obvious “*wherein geometric information for the plurality of target markers [of the medical device] is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, and wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system*”.

Gillies and Werp do not disclose or render obvious “*wherein geometric information for the plurality of target markers [of the medical device] is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy*”. The discussion above in conjunction with claim 23 is pertinent to this point.

Furthermore, Gillies and Werp do not disclose or render obvious “*wherein the MRI system is unable to detect or will disregard MRI signals of the target markers within the anatomy as noise without using the stored information for the plurality of target markers to lower an MRI signal detection threshold of the MRI system*”.

Gillies and Werp simply do not disclose that the MRI system is unable to detect or will disregard MRI signals of the target markers. Gillies discusses including microcoils etc. to improve visibility and the marker in Werp is clearly visible in MRI.

Furthermore, Gillies and Werp simply do not disclose **using the stored information** for the plurality of target markers to lower an MRI signal detection threshold of the MRI system.

Accordingly, for at least one or more of these reasons, claim 1, and its dependent claims, are believed to be allowable.

Independent claims 8, 34, 45, and 47, and their respective dependent claims, are believed to be allowable for one or more similar reasons.

35 U.S.C. §103(a) Rejection - Gillies, Werp, Young

Claims 2, 3, 11, 12, 25, 26, 36, and 37 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gillies in view of Werp and further in view of U.S. Patent No. 5,817,017 issued to Young et al. (hereinafter "Young"). Without admitting that these references could or should be combined, the Applicants respectfully submit that the present claims are allowable over Gillies, Werp, and Young.

Young discusses catheters and other medical devices including a non-metallic member having a paramagnetic ionic particles fixedly incorporated therethrough in order to provide enhanced detectability when viewed by MRI regardless of the orientation of the non-metallic member in the magnetic field. See e.g., the Abstract. Specifically, paramagnetic iron is a small iron and/or superparamagnetic particles are described.

However, Young does not remedy all of what is missing from Gillies and Werp for each of the independent claims. Accordingly, each of the independent claims, and their respective dependent claims, are believed to be allowable over Gillies, Werp, and Young.

Conclusion

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the cited art of record and are in condition for allowance. Applicants respectfully request that the rejections be withdrawn and the claims be allowed at the earliest possible date.

Request For An Extension Of Time

The Applicants respectfully petition for an extension of time to respond to the outstanding Office Action pursuant to 37 C.F.R. § 1.136(a) should one be necessary. Please charge our Deposit Account No. 02-2666 to cover the necessary fee under 37 C.F.R. § 1.17 for such an extension.

Charge Our Deposit Account

Please charge any shortage to our Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 2/17/09

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2/17/09

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